OCT 1 6 2001

510(k) Summary
Prepared 27 August 2001

K012900

Applicant's Name and Address

Beckman Coulter, Inc.
1000 Lake Hazeltine Dr.
Chaska, MN 55318

Contact Person: Mara Caler
858 621 4583

Alternate Contact Person: Denise Thompson
952 368 1202

Device Name

Trade Name - Access® Unconjugated Estriol Calibrators on the Access® Immunoassay Systems
Common Name – Unconjugated Estriol Calibrators
Classification name – Calibrators (21 CFR 862.1150)

Predicate Device

Beckman Coulter Access Unconjugated Estriol Calibrators

Device Description

The Access® Unconjugated Estriol Calibrators are liquid Calibrators to be used with the Access Immunoassay System.

Intended Use

The Access Unconjugated Estriol Calibrators set is a device intended for medical purposes for use in the Access Immunoassay System, to establish points of reference that are used in the determination of values in the measurement of estriol levels in human serum.

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Comparison to Predicate:

Data is presented to demonstrate substantial equivalence to the predicate.

Summary of Performance Data:

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to the Beckman Coulter Access Ultrasensitive hGH Calibrators already in commercial distribution. Stability studies of the Access Unconjugated Estriol Calibrators support the stability claim of a minimum of 24 months.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 1 6 2001

Ms. Mara Caler
Regulatory Specialist
Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, MN 55318

Re: k012900
Trade/Device Name: Access® Unconjugated Estriol Calibrators
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIT
Dated: August 27, 2001
Received: August 29, 2001

Dear Ms. Caler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known): K012900

Device Name: Access® Unconjugated Estriol Calibrators

Indications For Use:

The Access Unconjugated Estriol Calibrators set is a device intended for medical purposes for use in the Access Immunoassay System, to establish points of reference that are used in the determination of values in the measurement of estriol levels in human serum.

(PLEASE DO NOT WRITE BELOW THIS LINE--CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Kevin Alexander for Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012900